

**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**

  
Richard Zimmermann

## **PRELIMINARY AMENDMENT**

Box Patent Application  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Please amend the above-identified application as follows.

### **In The Specification:**

Please cancel the present title and substitute — — METHOD OF  
TREATING OR PREVENTING INCONTINENCE — — therefor

At page 1, following the heading “Cross Reference to Related Applications,” please replace the paragraph at lines 2-8, and substitute the following paragraph therefor:

— — This is a division of pending U.S. patent application Serial No. 09/599,213 filed June 22, 2000, which claims the benefit under 35 U.S.C. § 119(e) of U.S. provisional patent application Serial No. 60/141,968 filed July 1, 1999, U.S. provisional patent application Serial No. 60/144,131 filed July 16, 1999, U.S. provisional patent application Serial No. 60/158,256 filed October 6, 1999, and U.S. provisional patent application Serial No. 60/170,381 filed December 13, 1999, the disclosures of which are incorporated herein by reference. — —

**In The Claims:**

Claim 1 has been amended and is as follows:

1. A method of treating an individual suffering from incontinence, the method comprising the step of administering to the individual a therapeutically effective amount of a composition comprising a compound having a pharmacological selectivity of serotonin ( $K_1$ )/norepinephrine ( $K_2$ ) of at least about 5000.

Claims 18-31 have been canceled, without prejudice.

Claims 38 and 39 have been amended and are as follows:

38. A method of preventing incontinence in an individual, the method comprising the step of administering to the individual a therapeutically effective amount of a composition comprising a compound having a pharmacological selectivity of serotonin ( $K_1$ )/norepinephrine ( $K_2$ ) of at least about 5000.

39. A method of treating incontinence in an individual while diminishing adverse side effects, the method comprising the step of administering to the individual a total dose of about 0.1 to about 10 mg/day of an optically pure (S,S) reboxetine, or a pharmaceutically acceptable salt thereof, said optically pure (S,S) reboxetine being substantially free of (R,R) reboxetine.

Claim 41 has been amended and is as follows:

41. A method of treating or preventing incontinence, the method comprising the step of administering a therapeutically effective dose of racemic reboxetine or a pharmaceutically acceptable salt thereof to an individual.

Claims 42, 43, 52, and 53 have been canceled, without prejudice.

Claims 54-57 are newly added and are as follows:

54. The method of claim 1, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence.

55. The method of claim 38, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence.

56. The method of claim 39, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence.

57. The method of claim 41, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence.

## REMARKS

This preliminary amendment is being submitted in conjunction with a "Continuing Application Transmittal Under 37 C.F.R. 1.53(b)" (hereafter the "Transmittal"), which is a request for a divisional application. As noted in the Transmittal, the above-captioned application is a division of pending U.S. patent application Serial No. 09/599,213 filed June 22, 2000. In the '213 application, the U.S. Patent and Trademark Office issued an official action dated August 21, 2001, requiring the applicants "to elect a single disclosed species (i.e. a particular compound and a condition to be treated)." In response to the action, the applicants elected claims reciting an optically pure (S,S) reboxetine for the treatment of chronic pain. The present application includes claims (after entry of the amendments herein) reciting methods of treating or preventing incontinence in an individual. Accordingly, the methods recited herein by the amended claims do not read on the election made in the '213 application. It is submitted that no new matter is being introduced by the amendment.

The title of the application has been amended to be consistent with the claims. Furthermore, the specification has been amended to update the cross-reference to related applications.

Claims 1, 38, and 39 have been amended to recite methods of treating or preventing incontinence in an individual by administration of a therapeutically effective amount of a composition comprising a compound having a pharmacological selectivity of serotonin (K<sub>1</sub>)/norepinephrine (K<sub>2</sub>) of at least about 5000, such as an optically pure (S,S) reboxetine, or a pharmaceutically acceptable salt thereof, wherein the optically pure (S,S) reboxetine is substantially free of (R,R) reboxetine. Support for the amendment to these claims can be found in the claims and specification of the prior application, for example, in claim 18 and in the specification at page 19, line 6.

Claim 41 has been amended to recite a method of treating or preventing incontinence, wherein the method comprises the step of administering a therapeutically effective dose of racemic reboxetine or a pharmaceutically acceptable salt thereof to an individual. Support for the amendment can be found in claim 41 of the prior application. Support for the amendment also can be found in the specification of the prior application at, for example, page 12, lines 14-26, and page 28, lines 1-14.

Claims 18-31, 42, 43, 52, and 53 have been canceled, without prejudice.

Claims 54-57 are newly added and depend from claims 1, 38, 39, and 41, respectively. Support for these claims can be found in the specification at, for example, page 19, line 6, and page 28, lines 1-14.

Accordingly, by virtue of this amendment, claims 1-17, 32-41, 44-51, and 54-57 are pending.

Attached hereto (beginning at page 6) are sheets showing the changes made to the application by this amendment. The attached sheets are captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**."

Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, he is urged to contact the undersigned attorney.

Respectfully submitted,

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January 23, 2002

By

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In The Specification:**

Please cancel the present title and substitute — — METHOD OF TREATING OR PREVENTING INCONTINENCE — — therefor.

At page 1, following the heading “Cross Reference to Related Applications,” please amend the paragraph at lines 2-8 as follows:

This [application] is a division of pending U.S. patent application Serial No. 09/599,213 filed June 22, 2000, which claims the benefit under 35 U.S.C. § 119(e) of U.S. provisional patent application Serial No. 60/141,968 filed July 1, 1999, U.S. provisional patent application Serial No. 60/144,131 filed July 16, 1999, U.S. provisional patent application Serial No. 60/158,256 filed October 6, 1999, and U.S. provisional patent application Serial No. 60/170,381 filed December 13, 1999, the disclosures of which are incorporated herein by reference.

**In the Claims:**

Please amend claim 1 as follows:

1. (Amended) A method of [selectively inhibiting reuptake of norepinephrine,] treating an individual suffering from incontinence, the method comprising the step of administering to the individual a therapeutically effective amount of a composition [to an individual, the composition] comprising a compound having a pharmacological selectivity of serotonin ( $K_s$ )/norepinephrine ( $K_n$ ) of at least about 5000.

Please cancel claims 18-31, without prejudice.

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Please amend claims 38 and 39 as follows:

38. (Amended) A method of [treating a human suffering from a condition, or preventing said condition, wherein inhibiting reuptake of norepinephrine provides a benefit,] preventing incontinence in an individual, the method comprising the step of administering to the individual a therapeutically effective amount of a composition comprising a compound having a pharmacological selectivity of serotonin (K<sub>1</sub>)/norepinephrine (K<sub>2</sub>) of at least about 5000.

39. (Amended) A method of treating [a human suffering from a condition, or preventing said condition, wherein inhibiting reuptake of norepinephrine provides a benefit,] treating incontinence in an individual while diminishing adverse side effects, the method comprising the step of administering to the individual a total dose of about 0.1 to about 10 mg/day of an optically pure (S,S) reboxetine, or a pharmaceutically acceptable salt thereof, [to an individual,] said optically pure (S,S) reboxetine being substantially free of (R,R) reboxetine.

Please amend claim 41 as follows:

41. (Amended) A method of treating or preventing [a nervous system disorder] incontinence, the method comprising the step of administering a therapeutically effective dose of racemic reboxetine or a pharmaceutically acceptable salt thereof to an individual [, wherein said disorder is selected from the group consisting of at least one of an adjustment disorder, an age-associated learning and mental disorder, anorexia nervosa, apathy, an attention-deficit disorder due to general medical conditions, bipolar disorder, bulimia nervosa, chronic fatigue syndrome, chronic or acute stress, chronic pain, cyclothymic disorder, dysthymic disorder, fibromyalgia and other somatoform disorders, incontinence, mania, migraine headaches, obesity, peripheral neuropathy, post-traumatic stress disorder, premenstrual dysphoric disorder, a psychotic disorder, seasonal affective disorder, a sleep disorders, a specific developmental disorders, SSRI "poop out" syndrome, and TIC disorders].

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Please cancel claims 42, 43, 52, and 53, without prejudice.

Please add new claims 54-57 as follows:

— — 54. (New) The method of claim 1, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence.

55. (New) The method of claim 38, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence.

56. (New) The method of claim 39, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence.

57. (New) The method of claim 41, wherein incontinence is selected from the group consisting of stress incontinence, genuine stress incontinence, and mixed incontinence. — —